

CERTIFICATE OF ELECTRONIC FILING

I hereby certify that this correspondence is being submitted for electronic filing with the U.S. Patent and Trademark Office on

Date: March 13, 2008

Name: Barbara A. LaBarge

Signature: 

Our Case No. 8627/096 (PA-5245-RFB)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of)	
)	Group Art Unit: 3733
Fred T. Parker)	
)	Examiner: Anuradha Ramana
Serial No.: 09/815,567)	
)	Conf. No. 6497
Filed: March 23, 2001)	
)	
For: INTRODUCER SHEATH)	

PRE-APPEAL BRIEF REQUEST FOR REVIEW

MAIL STOP AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicant respectfully requests review of the final rejection of claims all 1-13, 15-20, 22 and 23, mailed February 1, 2008 in the above-identified application. A Notice of Appeal is being filed concurrently, and is included herewith. Review is requested for the reasons indicated hereinafter.

Section 112 rejections:

In the final Office Action of February 1, 2008, the Examiner rejected claims 1-13, 15-20 and 22 under 35 USC 112, 1st and 2nd paragraphs. Specifically, the Examiner contends that the term "uniformly spaced coil turns" was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention (1st paragraph), and that the claims are indefinite as a result of this terminology (2nd paragraph).

In response, Applicant states that this terminology was added to independent claims 1 and 22 as a result of the Examiner's contention in the previous action that:

"Applicant's arguments are not directed to claim limitations since claim 1 does not recite that the spacing between the turns is uniform." Applicant had not previously included this term in the claims because it was not believed necessary to distinguish the cited art. However, in order to advance prosecution, the term was added in Applicant's most recent Response to address the concerns raised by the Examiner. At that time, Applicant stated that support for the amendment was provided at Figs. 2-4 of the application, which illustrate a coil having uniformly spaced turns. Citation was also made to Col. 4, lines 9-16, and Figs. 2-4 of Applicant's earlier U.S. Patent No. 5,380,304, to illustrate the meaning of this term in the art. Figs. 2-4 of the '304 patent are virtually the same as Figs. 2-4 of the instant application. Applicant respectfully submits that one skilled in the art would have no difficulty understanding the meaning of this terminology.

Applicant does not believe that inclusion of this term is crucial to patentability. In the event that the art rejections are overcome, and this rejection is maintained, Applicant believes that acceptable alternative language can be readily provided to address the Section 112 rejections, without the necessity of action by the BPAI.

Section 103(a) rejections:

Claims 1-2, 4-5, 10-13, 15-20, 22 and 23 were rejected under 35 U.S.C. §103(a) over Horrigan in view of Park. For purposes of brevity, Applicant will limit his remarks to these claims. Further discussion of the rejections of the remaining claims (3 and 6-9) is not necessary for resolution of the issues raised herein.

The sheath of claim 1 includes, among others, an inner tube, a wire coil wound around the inner tube, and first and second outer tubes aligned in order of decreasing durometer toward the distal end of the sheath. Horrigan was cited by the Examiner as disclosing a sheath having some features in common with the sheath of claim 1, but differing in the type of reinforcement.¹ Park was cited for teaching a catheter section or sheath "with equivalent forms of stiffening members or reinforcement for kink resistance, i.e., a flat wire coil, a round wire coil, and a braided wire coil." OA, page 3. According to

¹ "Horrigan et al do not disclose the use of a flat wire coil, a round wire coil or a braided wire coil as a reinforcement means." OA, page 3.

the Examiner, it would have been obvious to substitute the wire braid of Horrigan with a coil as disclosed in Park. OA, page 3.

Applicant presented a great deal of evidence to the Examiner to support the contention that the substitution was not obvious, and to explain when one skilled in the art would utilize a coil instead of a braid as a sheath reinforcement. In his Declaration, Thomas Osborne, explained the difference between the two types of reinforcement, and provided photographs illustrating differences in kink resistance of the two reinforcements. Mr. Osborne disagreed with the Examiner's premise that a braid and coil are equivalent for resistance to kinking, and disagreed that such a conclusion can be reached from the teaching of the Park patent. T.O. Decl. ¶ 6. With regard to certain properties of a sheath, such as stiffness, pushability or torqueability, a braid reinforcement is superior to a coil reinforcement. When it is desired to maximize the kink resistance of a sheath, a coil reinforcement is superior to a braid reinforcement. T.O. Decl. ¶¶ 7, 14.

In his declaration, Dr. Sathya Kaliyamoorthy described the results of a Finite Element Analysis ("FEA") computer simulation test that he carried out to compare the kink resistance of a sheath representative of a braided sheath taught in Horrigan, with the kink resistance of a sheath *otherwise similar to the Horrigan sheath* but having a coil reinforcement instead of the braid reinforcement. S.K. Decl. ¶5. The aim of the test was to establish whether a sheath having a coil reinforcement exhibited greater kink resistance than an otherwise similar sheath having a braid reinforcement. In carrying out his simulations, Dr. Kaliyamoorthy carefully attempted to compare Applicant's invention/results thereof with those of the closest prior art (Horrigan). S.K. Decl. ¶¶ 5, 6.

Dr. Kaliyamoorthy concluded that the braid-reinforced sheath representative of the Horrigan sheath quickly began to lose its normalized diameter upon bending, and kinked at a relatively small bending angle of about 21 degrees. At this angle, the normalized stent diameter was reduced to about 0.6, or in other words, the circularity of the sheath was about 60% of normal diameter. Upon further bending, the braid-reinforced sheath lost its entire diameter at a bending angle of about 47 degrees. (S.K. Decl. ¶ 10.) On the other hand, at the same bending angle of 21 degrees, the coil-reinforced sheath maintained a circularity of about 96%. This coil-reinforced sheath

maintained a circularity in excess of 70% of the original diameter until reaching a bending angle of 67 degrees. Thus, it was demonstrated that the coil-reinforced sheath was able to be bent to a much greater angle (67 degrees vs. 21 degrees) than the braid-reinforced sheath, while maintaining a circularity greater than 70% of its original diameter. (S.K. Decl. ¶¶ 11, 12.)

To place this in a real-world context, a stent or other interventional medical device having a diameter approaching that of the normalized diameter of the bent sheath can be passed through the coil-reinforced sheath, until the sheath is bent to an angle of 67 degrees. On the other hand, with a braid-reinforced sheath, the sheath loses much of its normalized stent diameter at a bending angle of only 21 degrees, and loses its entire diameter (i.e., it is fully kinked) at 47 degrees. This sheath would have only limited utility when used for passage of a small diameter stent therethrough once it reaches a bending angle of 21 degrees, and would have no utility for such passage at 47 degrees. The FEA simulation clearly test showed that the sheath having a coil reinforcement is able to be tracked through vessels having bending angles at which the sheath having a braid reinforcement would be unusable. This difference can be critical when attempting to position a medical interventional device, such as a stent, at branched or otherwise tortuous area of the vasculature. In many such cases, placement utilizing a coil-reinforced sheath would be successful, while an attempted placement with a braid-reinforced sheath would fail.

The secondary Park reference teaches a complex solution to the problem of providing access to a target site through increasingly small vessels. The solution to this problem advocated by Park differs considerably from the teachings of the present invention. Park utilizes a catheter having a distal tip section that includes a forming member, such as a woven braid or a coil, formed of a super-elastic material. The super-elastic forming member is placed in the catheter section, and is movable from a first to a second shape upon application of heat.

The Examiner stated that Park et al "teach the substitution of coils for braids (Figs. 7-9) and demonstrate the equivalence of one known type of reinforcement, for e.g. braid, for another, for e.g. coil, to yield predictable results..." Applicant disputes the Examiner's rationale that the various reinforcements recited in Park are equivalent, as

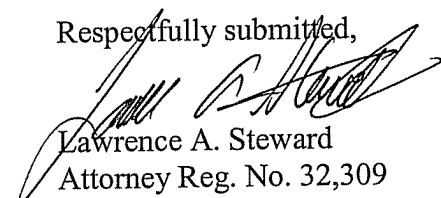
alleged by the Examiner, and that Park teaches such equivalence. Applicant submits that those skilled in the art are well aware that a coil and a braid are separate reinforcements with specific purposes, and although they can perhaps be considered interchangeable for limited uses, they are generally used for very specific purposes.

Applicant disputes that any such conclusion is taught or suggested in Park. When properly construed, it is clear that Park makes no claim of equivalence among different types of reinforcements, nor does he even suggest such equivalence. Rather, Park teaches that *superelastic* distal reinforcements, of whatever construction, are formable (e.g., bendable) upon application of heat from a first, constrained, shape to a second, equilibrium, shape. The teaching is said to be beneficial when applied to catheters having either a braid or a coil reinforcement. There is no teaching or suggestion of equivalence or interchangeability between such reinforcements in normal use, nor is the patent even concerned with making such a conclusion. Applicant respectfully submits that the Examiner is reading too much into Park's statements regarding the breadth of his invention. It is clear that Park does not discuss any benefits in kink resistance that may be achieved when a coil reinforcement is utilized instead of a braid, or vice versa, and in fact, provides no reasons why one skilled in the art would ever want to use a coil.

Conclusion:

Based on the foregoing, Applicant respectfully asserts that the final rejection of the cited claims is erroneous, and requests that the panel issue a decision so indicating.

Respectfully submitted,



Lawrence A. Steward
Attorney Reg. No. 32,309
Attorney for Applicants

BRINKS HOFER GILSON & LIONE
CUSTOMER NO. 48004
Telephone: 317-636-0886
Facsimile: 317-634-6701